CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 020779, S022

CHEMISTRY REVIEW(S)

VIRACEPT 1250 mg should be approved with the labeling changes negotiated by DAVDP and Agrouron. Agouron has agreed to submit the final study 542 report after all patients have received 48 weeks of dosing. In addition they have agreed to study BID dosing of VIRACEPT in pediatric patients.

/S/

Jeffrey S. Murray, M.D., M.P.H.
Medical Team Leader

APPEARS THIS WAY
ON ORIGINAL